MAY - 5 2000

K 001263

Summary of Safety and Effectiveness:

Submitter's Name:	ESC Sharplan.
Submitter's Address:	100 Morse Street Norwood, MA 02062
Telephone Number:	781-278-7600
Fax Number:	781-278-7700
Name of Device:	200 micron Fiber Sharplan Model 2040 Pulsed CTH: YAG Surgical Laser
Predicate Device:	300-1000 micron Fiber Sharplan Model 2040 Pulsed CTH: YAG Surgical Laser K952277
Description of the Device:	The 200 micron optical delivery fiber has a germanium doped low OH core and a 20 micron low OH silica cladding. The total length is 3000mm with a polyamide coating and a 2mm C-Flex jacket extending 1500mm from the proximal end. The fiber is bare for the last distal 1 mm with a highly polished surface. The proximal end has a free standing, high power SMA 905 connector which serves as the interface with the holmium laser. The fiber is provided sterile. The fiber is used to deliver pulses from the laser to the operating area.
Substantial Equivalence:	The 200-micron fiber has the same indications for use as the predicate fibers, is constructed in a similar manner, and is made from similar materials and has the same design principles. The differences are minor and consist of a polyamide coating and a C-Flex jacket, which have been

found to be compliant with ISO10993-1. The fiber is supplied sterile.

Indications for Use:

Incision/excision, ablation, vaporization, and coagulation of soft tissue and firm cartilage (to include but not limited to skin, subcutaneous tissue, striated and smooth muscle, mucous membrane, lymph vessels and nodes, organ and glands) for the following surgical applications:

General Surgery

Otolaryngology (ENT) and Head and Neck Surgery (Open/endoscopic)

Dacryorhinoplasty

Open, Arthroscopic/Microdiskectomy and Percutaneous Diskectomy Surgery

Arthroscopic/Orthopedic Surgery (*Open/endoscopic*) (All joints)

Urology and Urolithiasis (soft tissue, open/endoscopic)

Summary:

Biocompability studies were performed to demonstrate safety and compliance with ISO10993-1 and ISO10993-7. Performance of the fiber was tested after exposure to extreme thermal challenges for transmission properties, flexibility and dimensional stability with little difference in values. Hazard and risk analysis was determined with validation and verification performed where appropriate. Bioburden measurements were determined to assure a SAL of 10^{-6}

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2000

Dr. Zvi Ladin
Corporate Vice President, Clinical
and Regulatory Affairs
ESC Sharplan
100 Morse Street
Norwood, Massachusetts 02062

Re: K001263
Trade Name: Sharplan Model 2040 Pulsed CTH:YAG Surgical Laser System
Regulatory Class: II
Product Code: GEX
Dated: April 14, 2000
Received: April 19, 2000

Dear Dr. Lavin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Bechner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K001263

510(k) Number (if known) K001263

Device Name: Sharplan Model 2040 Pulsed CTH:YAG Surgical Laser System

Indications For Use:

Incision/excision, ablation, vaporization, and coagulation of soft tissue and firm cartilage (to include but not limited to skin, subcutaneous tissue, striated and smooth muscle, mucous membrane, lymph vessels and nodes, organ and glands) for the following surgical applications:

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Dacryorhinoplasty

Open, Arthroscopic/Microdiskectomy and Percutaneous Diskectomy Surgery

Arthroscopic/Orthopedic Surgery (Open/endoscopic) (all Joints)

Urology and Urolithiasis (soft tissue, open/endoscopic)

Donna R. Vachuska

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001263

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